employee, in cases where the provisions of either 28 U.S.C. 2679 or 38 U.S.C. 4116 are not applicable, by the payment of available funds, at any time; provided that: the alleged conduct giving rise to the personal damage claim was taken within the employee's scope of employment and that such settlement or compromise is in the interest of the Veterans Administration, as determined by the Administrator or his designee.

(3) Absent exceptional circumstances as determined by the Administrator or his designee, the Agency will not entertain a request either to agree to indemnify or to settle a personal damage claim before entry of an adverse verdict, judgment, or award.

(4) A Veterans Administration employee may request indemnification to satisfy a verdict, judgment, or award entered against that employee. The employee shall submit a written request, with appropriate documentation including copies of the verdict, judgment, award, or settlement proposal, in a timely manner to the Veterans Administration General Counsel, who shall make a recommended disposition of the request. Where the Veterans Administration determines it appropriate, the Agency shall seek the view of the Department of Justice. The General Counsel shall forward the employee request for indemnification, and the accompanying documentation, with the General Counsel's recommendation to the Administrator for decision.

(5) Any payment under this section either to indemnify a Veterans Administration employee or to settle or compromise a personal damage claim shall be contingent upon the availability of appropriated funds of the Veterans Administration.

(d) *Attorney-client privilege.* Attorneys employed by the Veterans Administration who participate in any process utilized for the purpose of determining whether the Agency should request the Department of Justice to provide representation to an Agency employee sued, subpoenaed or charged in his individual capacity, or whether attorneys employed by the Veterans Administration should provide assistance in the representation of such an Agency employee, undertake a full and traditional attorney-client relationship with the employee with respect to application of the attorney-client privilege. If representation is authorized, Veterans Administration attorneys who assist in the representation of an employee also undertake a full and traditional attorney-client relationship with the employee with respect to the attorney-client privilege. Any adverse information communicated by the client-employee to an attorney during the course of such attorney-client relationship shall not be disclosed to anyone, either inside or outside the Veterans Administration, other than attorneys responsible for representation of the employee, unless such disclosure is authorized by the employee.

* * * * *

[FR Doc. 89-2689 Filed 2-3-89; 8:45 am]
BILLING CODE 8320-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 57

Grants for Health Professions Projects in Geriatrics

AGENCY: Public Health Service, HHS.

ACTION: Final regulations.

SUMMARY: These final regulations set forth requirements which govern the program for Grants for Health Professions Projects in Geriatrics, authorized by section 788(d) of the Public Health Act (the Act), as amended by the Health Professions Training Assistance Act of 1985, and Title VI—Geriatric Training Amendments of 1986.

DATE: These regulations are effective February 6, 1989.

FOR FURTHER INFORMATION CONTACT: William Koenig, Deputy Chief, Associated Health Professions Branch, Division of Associated and Dental Health Professions, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8-103, 5600 Fishers Lane, Rockville, Maryland 20857; telephone number: 301 443-6887.

SUPPLEMENTARY INFORMATION: On May 6, 1988, the Assistant Secretary for Health, Department of Health and Human Services, with the approval of the Secretary, published in the **Federal Register** (53 FR 16293), a Notice of Proposed Rulemaking (NPRM) to add a new Subpart 00 to Part 57 of Title 42 of the Code of Federal Regulations to implement regulations governing Grants for Health Professions Projects in Geriatrics, authorized by section 788(d) of the Public Health Service Act, as amended by Pub. L. 99-129, the Health Professions Training Assistance Act of 1985, enacted on October 22, 1985, and Title VI—Geriatric Training of Pub. L. 99-660, enacted on November 14, 1986. Section 788(d) authorizes the Secretary to make grants to and enter into contracts with accredited schools of medicine, osteopathy, dentistry, pharmacy, optometry, podiatry, veterinary medicine, chiropractic, allied health, and programs for the training of physician assistants to assist in meeting the costs of projects to:

(a) Improve the training of health professionals in geriatrics;

(b) Develop and disseminate curricula relating to the treatment of the health problems of elderly individuals;

(c) Expand and strengthen instruction in methods of such treatment;

(d) Support the training and retraining of faculty to provide such instruction (other than training and retraining of faculty for schools of medicine and osteopathy);

(e) Support continuing education of health professionals and allied health professionals who provide such treatment; and

(f) Establish new affiliations with nursing homes, chronic and acute disease hospitals, ambulatory care centers, and senior centers in order to provide students with clinical training in geriatric medicine.

The Department proposed to implement section 788(d) by awarding grants for projects which support one or more of the statutory purposes and provide assistance to either a single health professions school or program, or a group of such schools or programs.

The NPRM included a definition for "training and retraining of faculty" to mean "a program to train and retrain faculty to provide geriatric instruction which is not a 1-year retraining program for faculty in schools of medicine and osteopathy in geriatrics or a 1-year or 2-year internal medicine or family medicine fellowship program as identified in section 788(e)(3) of the Act."

The Department also proposed that in determining the funding of applications approved under this program, the Department will announce, and solicit public comment on, any special factors related to national needs in periodic notices in the **Federal Register**.

The public comment period for this NPRM ended July 5, 1988. The Department received four comments. A summary of the comments and the Department's response are set forth below.

The majority of the comments concerned the definition of a "health professions school" as it pertains to eligibility to be the recipient of a grant under section 788(d)(1) of the Act, and the definition of a "health professional"

as it pertains to individuals eligible to participate in training under section 788(d)(1) (A)–(F) of the Act. One respondent noted that although "nurse" and "nurse practitioner" were included in the definition of "health professional," nursing schools were not included in the definition of "health professions school." The reason that schools of nursing were excluded from the definition of "health professions schools" and, consequently, from those entities which are eligible to receive a grant, is that the statute does not authorize their inclusion.

The NPRM defined a "health professions school" to mean "any accredited school of medicine, dentistry, osteopathy, pharmacy, optometry, podiatry, veterinary medicine, public health, and chiropractic as defined in section 701(4) of the Act and as accredited in section 701(5) of the Act." "Health professional" was defined as "any allopathic or osteopathic physician, dentist, optometrist, podiatrist, pharmacist, nurse, nurse practitioner, physician assistant, chiropractor, or allied health professional." Section 788(d)(1) authorizes the Secretary "to make grants to and enter into contracts with accredited health professions schools referred to in section 701(4) or 701(10) and programs referred to in section 701(8) * * *." Schools of nursing are not included in the types of schools identified in section 701(4) or covered by section 701 (8) or (10). Thus, schools of nursing are not eligible to be the direct recipient of a grant or contract under section 788(d). However, schools and other entities not eligible to receive a grant or contract may participate in projects covering the broad range of geriatric education activity described in section 788(d)(1) (A)–(F). For example, a school of medicine which is eligible as a grantee can include a school of nursing as part of a collaborative project proposal. Although schools of nursing are not eligible to be the recipient of a grant under section 788(d), the Department believes that the key role of professional nurses in providing geriatric services makes it essential that they be included in comprehensive geriatric education initiatives.

The distinction between eligibility to be a grantee and a participating health professional also applies to an inquiry received concerning whether schools of psychology would be eligible for support. Although these schools are not eligible to be grantees under section 701(4), 701(8) or 701(10) of the Act, the Secretary believes that these professions should be listed under the definition of "health professionals" as potential trainees under these projects. Therefore, the definition of a "health professional" has been changed to include clinical psychologists and health administrators.

It was also suggested that schools of social work should be included in the definition of "health professions schools." The Department believes that the proposed regulation adequately provides for the effective participation of schools of social work in projects supported under section 788(d).

Several respondents advocated specific types of activities for support, such as: The dissemination and use of existing, as opposed to developing new, curricula; efforts to recruit potential geriatric practitioners; affiliations between geriatric education programs and State units on aging and area agencies on aging; and targeted short-term faculty development for the entire faculty of a department of family medicine.

The Department notes that all of these activities could be included under the broad project purposes set forth in § 57.4004. In fact, some of the existing efforts cited have already been undertaken through Geriatric Education Centers and other projects funded under section 788(d) of the Act. The Secretary believes a flexible approach for funding permits the effective use of scarce educational resources and multidisciplinary approaches. Therefore, § 57.4004 has been retained as proposed.

These final regulations include technical and clarifying revisions to incorporate current departmental grants policy language. Since the revisions are technical in nature, the Secretary has determined pursuant to 5 U.S.C. 553 and departmental policy that is unnecessary and impractical to follow proposed rulemaking procedures. These revisions are summarized below according to the section numbers and titles of the regulations.

1. Revise § 57.4003, entitled "*Who is eligible to apply for a grant?*", by inserting in the footnote a parenthetical phrase, which provides the PHS form and OMB approval numbers for the application form and instructions.

2. Revise § 57.4005(b), entitled "*How will applications be evaluated?*", by removing the words "priority for" and adding the word "of" after the word "funding" to be consistent with recent departmental policy language regarding funding preferences.

3. Revise § 57.4006(b), entitled "*How long does grant support last?*", by removing the second sentence in paragraph (b) which is repetitive of language regarding the submission of a separate application to receive consideration for continued support stated in the last sentence of paragraph (c) of this section.

4. Revised § 57.4009, entitled "*What other audit and inspection requirements apply to grantees?*", by adding the current OMB information collection approval number at the end of the section text.

"On May 10, 1988, the Office of Management and Budget published in the **Federal Register** (53 FR 16618, Part II) revised regulations to implement amendments to the Paperwork Reduction Act of 1980, made by the Paperwork Reduction Reauthorization Act of 1986. These revised regulations set forth additional requirements for information collections which agencies must publish in the preamble of regulations. In compliance with this requirement, the public response burden concerning information collections clearance for this grant program is presented in the preamble. The inclusion of these burdens, however, does not change the statutory provisions of the regulations that govern the Grants for Health Professions Projects in Geriatrics program."

Regulatory Flexibility Act and Executive Order 12291

These regulations govern a financial assistance program in which participation is voluntary. The rule will not exceed the threshold level of $100 million established in section (b) of Executive Order 12291. For these reasons, the Secretary has determined this rule is not a major rule under Executive Order 12291 and a regulatory impact analysis is not required. Further, because the rule does not have a significant economic impact on a substantial number of small entities, a regulatory flexibility analysis under the Regulatory Flexibility Act of 1980 is not required.

Paperwork Reduction Act of 1980

This final rule contains information collections which have been approved by the Office of Management and Budget under the Paperwork Reduction Act of 1980 and assigned control number 0915–0128. The title, description, and respondent description of the information collections are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching

existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Grants for Health Professions Projects in Geriatrics.

Description: The audit requirement for 42 CFR 57.4009 is needed to account for expenditures of grant funds by health professions schools.

Description of Respondents: Nonprofit institutions.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN:

Section No.	Annual No. of respondents	Annual frequency [1]	Average burden per response [1]	Annual burden hours
57.4009	25	1	4 hours	100 hours.

[1] Audits are estimated to take approximately 8 hours to complete. Since the audits in § 57.4009 are to be conducted biennially, the average burden per response has been reduced by one-half, or 4 hours, to indicate the annual response burden.

We received no public comments on the estimated public reporting burden, and it remains the same as in the proposed rule.

List of Subjects in 42 CFR Part 57

Dental health, Health facilities, Education of the disadvantaged, Health professions, Educational facilities, Loan programs-health, Educational study program, Medical and dental schools, Emergency medical services, Scholarships and fellowships, Grant programs-health, Student aid.

Accordingly, a new Subpart 00 to Part 57 of Title 42 of the Code of Federal Regulations is added, as set forth below.

Dated: November 2, 1988.

Robert E. Windom,

Assistant Secretary for Health.

Approved: December 2, 1988.

Otis R. Bowen,

Secretary.

[*Catalog of Federal Domestic Assistance*, No. 13.969, Grants for the Training of Health Professions in Geriatrics]

PART 57—GRANTS FOR CONSTRUCTION OF TEACHING FACILITIES, EDUCATIONAL IMPROVEMENTS, SCHOLARSHIPS, AND STUDENT LOANS

1. 42 CFR Part 57 is amended by adding a new Subpart 00, entitled "Grants for Health Professions Projects in Geriatrics" to read as follows:

Subpart 00—Grants for Health Professions Projects in Geriatrics

Sec.

Subpart 00—Grants for Health Professions Projects in Geriatrics

Authority: Sec. 215 of the Public Health Service Act, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); sec 788(d) of the Public Health Service Act, 99 Stat. 542 (42 U.S.C. 295g–8).

§ 57.4001 To what projects do these regulations apply?

These regulations apply to grants to eligible schools and programs under section 788(d) of the Public Health Service Act for geriatric training projects.

§ 57.4002 Definitions.

"Act" means the Public Health Service Act, as amended.

"Allied health professional" means an individual who has received a certificate, an associate degree, a bachelor's degree, a master's degree, a doctoral degree, or postbaccalaureate training, in a science relating to health care and meets the requirements as established in section 701(13) of the Act.

"Budget period" means the interval of time into which the project period is divided for budgetary and reporting purposes, as specified in the grant award document.

"Continuing education" means structured educational programs for practicing health professionals and allied health professionals for the purpose of improving the knowledge and skills in geriatrics of such practitioners with respect to treatment of the health problems of elderly individuals.

"Geriatrics" is the total health and social care of the elderly.

"Geriatric Medicine" means the prevention, diagnosis, care and treatment of illness and disability as required by the distinct needs of the elderly.

"Health professional" means any allopathic or osteopathic physician, dentist, optometrist, podiatrist, pharmacist, nurse, nurse practitioner, physician assistant, chiropractor, clinical psychologist, health administrator, or allied health professional.

"Health professions school" means any school of medicine, dentistry, osteopathy, pharmacy, optometry, podiatry, veterinary medicine, public health, and chiropractic as defined in section 701(4) of the Act and as accredited in section 701(5) of the Act.

"Nonprofit" means an entity owned and operated by one or more corporations or associations, no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

"Program for the training of physician assistants" means any educational programs as defined in section 701(8) of the Act.

"Project director" means an individual designated by the grantee in the grant application and approved by the Secretary to direct the project being supported under this subpart.

"Project period" means the total time for which support for a project has been approved including any extensions of the project.

"School of allied health" means a public or nonprofit private junior college, college, or university which provides or can provide a program of education to enable individuals to become allied health professionals or to provide additional training for allied health professions and which meets the criteria set forth in section 701(10) of the Act.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"State" means, in addition to the several States, only the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, the Trust Territory of the Pacific Islands (the Republic of Palau), the Republic of the Marshall Islands, and the Federated States of Micronesia.

"Training and retraining of faculty" means a program to train and retrain faculty to provide geriatric instruction which is not a 1–year retraining program for faculty in schools of medicine and osteopathy in geriatrics or a 1–year or 2–year internal medicine or family medicine fellowship program as identified in section 788(e)(3) of the Act.

§ 57.4003 Who is eligible to apply for a grant?

Any public or nonprofit health professions school, school of allied health, or program for the training of physician assistants located in a State may apply for a grant under this subpart. Each eligible applicant desiring a grant under this subpart shall submit an application in the form and at the time the Secretary may prescribe.[1]

§ 57.4004 Program requirements.

(a) The Secretary will award grants to meet the cost of carrying out one or more of the following six purposes:

(1) Improve the training of health professionals in geriatrics;

(2) Develop and disseminate curricula relating to the treatment of the health problems of elderly individuals;

(3) Expand and strengthen instruction in methods of geriatric treatment;

(4) Support the training and retraining of faculty;

(5) Support continuing education of health professionals and allied health professionals who provide geriatric treatment; and

(6) Establish new affiliations with nursing homes, chronic and acute disease hospitals, ambulatory care centers, and senior centers in order to provide students with clinical training in geriatric medicine.

Projects may include one or more of the activities in paragraph (a)(1)–(6) of this section for one or more types of health professionals as defined in § 57.4002 of this subpart.

(b) Each project must evaluate the program systematically, including the determination of a baseline at the outset of the project and the measurement of the degree to which program and educational objectives are met.

§ 57.4005 How will applications be evaluated?

(a) After a peer review group, as required by section 788(d)(2)(B) of the Act, composed principally of non-Federal experts, makes recommendations concerning each application, the Secretary will consult with the National Advisory Council on Health Professions Education, established in section 702 of the Act, with respect to such applications. The Secretary will decide which applications to approve by considering, among other factors:

(1) The degree to which the proposed project adequately provides for the project requirement described in § 57.4004;

(2) The extent to which the rationale and specific objectives of the project are based upon a needs assessment of the status of geriatrics training in the institutions to be assisted and/or the geographic area to be served;

(3) The ability of the project to achieve the project objectives within the proposed geographic area;

(4) The adequacy of educational facilities and clinical training settings to accomplish objectives;

(5) The adequacy of organizational arrangement involving professional schools and other organizations necessary to carry out the project;

(6) The adequacy of the qualifications and experience in geriatrics of the project director, staff and faculty;

(7) The administrative and managerial ability of the applicant to carry out the proposed project in a cost-effective manner; and

(8) The potential of the project to continue on a self-sustaining basis.

(b) In determining the funding of applications approved under paragraph (a) of this section, the Secretary will consider any special factors relating to national needs as the Secretary may from time to time announce in the **Federal Register**.

§ 57.4006 How long does grant support last?

(a) The notice of grant award specifies the length of time the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed 5 years.

(b) Generally, the grant will initially be funded for 1 year, and subsequent continuation awards will also be for 1 year at a time. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of such factors as the grantee's progress and management practices, existence of legislative authority, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application nor the award of any grant shall commit or obligate the United States in any way to make any additional, supplemental, continuation or other award with respect to any approved application or portion of an approved application. For continuation support, grantees must make separate application at such times and in such a form as the Secretary may prescribe.

§ 57.4007 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in Subpart Q of 45 CFR Part 74, and these regulations.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

(c) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

§ 57.4008 What additional Department regulations apply to grantees?

Several other regulations apply to grants under this subpart.

These include, but are not limited to:

42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure

45 CFR Part 16—Procedures of the Departmental Grant Appeals Board

45 CFR Part 46—Protection of human subjects

45 CFR Part 74—Administration of grants

45 CFR Part 75—Informal grant appeals procedures

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80 of this Title

[1] Applications and instructions (Form PHS 6025–1, OMB #0915–0060) may be obtained from the Grants Management Officer, Bureau of Health Professions, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

45 CFR Part 83—Regulation for the administration and enforcement of sections 799A and 845 of the Public Health Service Act [1]

45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR Part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

§ 57.4009 What other audit and inspection requirements apply to grantees?

Each grantee must, in addition to the requirement of 45 CFR Part 74, meet the requirements of section 705 of the Act, concerning audit and inspection.

(Approved by the Office of Management and Budget under control number 0915-0128.)

§ 57.4010 Additional conditions.

The Secretary may impose additional conditions in the grant award before or at the time of the award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

[FR Doc. 89-2701 Filed 2-3-89; 8:45 am]

BILLING CODE 4160-15-M

Health Care Financing Administration

42 CFR Part 405

[BERC-408-F]

Medicare Program; Payment for Kidneys Sent to Foreign Countries or Transplanted in Patients Other Than Medicare Beneficiaries

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: These final regulations exclude from Medicare payments made to organ procurement organizations the costs associated with kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

In addition to reducing Medicare expenditures by eliminating Medicare subsidization of the costs of kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries, we intend these regulations to increase the availability of kidneys to Medicare beneficiaries who are suitable transplant candidates. This could result in medical and social benefits for transplanted patients, and reductions in Medicare expenditures because kidney transplantation is more cost-effective than maintaining beneficiaries on kidney dialysis.

DATE: These regulations are effective on March 8, 1989.

FOR FURTHER INFORMATION CONTACT: Mark Horney, (301) 966-4554.

SUPPLEMENTARY INFORMATION:

I. Background

The Social Security Amendments of 1972 (Pub. L. 92-603) extended Medicare coverage to individuals with end stage renal disease (ESRD) who require dialysis or transplantation. Section 1881 of the Social Security Act (the Act) provides for Medicare payment for kidney transplantation. One of the major components of kidney transplantation is the retrieval of organs through an organ procurement organization (OPO). An OPO, whether independent or hospital-based, is defined in Medicare regulations (42 CFR 485.302 as published on March 1, 1988, 53 FR 6526) as an organization that performs or coordinates the performance of retrieving, preserving, and transporting organs and maintains a system to locate prospective recipients for available organs.

Since the inception of the ESRD program, OPOs have procured kidneys from donors. Once kidneys are retrieved, the OPO searches for and identifies acceptable recipients and coordinates transporting these kidneys to other OPOs, transplant centers or foreign countries. The OPO places kidneys with a transplant organization based on the best possible match of tissue type, blood type, etc., as well as consideration for cold ischemic time (the amount of time a kidney has been outside the body and packed on ice), transportation distance, etc.

The Medicare program pays separately for kidney acquisition services and kidney transplantations. The OPO bills each of the organizations that receive kidneys a standard acquisition charge for each kidney. The standard acquisition charge reflects the cost of removing, preserving, and transporting a kidney, etc. While a hospital-based OPO develops its own charge, an independent OPO's charge is developed by its Medicare fiscal intermediary based on the OPO's costs of operating. These standard acquisition charges become the interim payment for each OPO. The OPO submits its cost of operating on a cost report at the end of its fiscal year. The cost report details both the costs of procuring kidneys and the amounts received from the shipment of kidneys to other OPOs, transplant centers, military hospitals, Veterans Administration (VA) hospitals, and foreign countries. The net difference between the total cost and the total amount received represents the amount due to or from the intermediary.

The Medicare program has always paid the total costs of OPOs because we assumed that all kidneys procured were for Medicare beneficiaries. However, we now realize that this assumption is incorrect and that technology has allowed a significant number of kidneys to be shipped overseas. Since the Medicare program has been paying the cost of procuring kidneys shipped overseas or transplanted into patients other than Medicare beneficiaries, we believe that some action needs to be taken. It is now necessary to amend the regulations in order to effectuate the statutory principles embodied in section 1861(v)(1)(A) of the Act. Section 1861(v)(1)(A) of the Act requires that the cost of services be borne by the appropriate payer. Accordingly, the cost associated with the kidneys not used by Medicare beneficiaries must be borne by the responsible individual or third party payer. Medicare is precluded from paying any costs associated with kidneys not used by Medicare beneficiaries.

On March 2, 1988, we published a proposed rule (53 FR 6672) that would exclude the costs associated with kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries from Medicare payments made to OPOs.

II. Provisions of the Proposed Rule

The preamble to the March 2, 1988 proposed rule (53 FR 6673) includes an explanation of current kidney transplantation practices and the proposed regulation provisions and rationale. The final regulation provisions that appear in section IV of this preamble restate the proposed regulation provisions, with the few exceptions noted in that section.

III. Analysis of and Responses to Public Comments

We received 10 timely comments in response to the March 2, 1988 proposed rule. Comments were submitted by OPOs, a nurses' association, and two group health insurance organizations.

[1] Section 799A of the Public Health Service Act was redesignated as section 704 by Pub. L. 94-484; section 845 of the Public Health Service Act was redesignated as section 855 by Pub. L. 94-63.

The major comments and our responses follow.

Comment: Some commenters suggested that we require that all organs be procured through the national Organ Procurement and Transplantation Network (OPTN) before sending them to a foreign country. They also believe that kidneys should not be sent to a foreign country unless all costs are paid by the foreign transplant center.

Response: All Medicare-certified OPOs are required to query the OPTN system for a suitable recipient in the United States if the procured organs cannot be used locally. We agree that this is a necessary requirement to ensure that there is not a suitable recipient in this country. However, it is not the responsibility of the OPTN to arrange or coordinate the exportation or importation of organs, and OPSs are free to make these arrangements directly. As for payment, it is the responsibility of the OPO, not the OPTN, to assure that the foreign transplant center pays the costs of the organ.

Comment: One commenter stated that Canada should not be characterized as a foreign country because of its willingness to share organs.

Response: We cannot accept this suggestion. Section 1862(a)(4) of the Act and Medicare regulations at 42 CFR 405.313 preclude reimbursement by the Medicare program for services performed outside the United States. Therefore, any organs sent to recipients in Canada will be treated as organs sent to a foreign country. Of course, nothing in this requirement need impede organ transfers between the two countries provided that proper cost accounting and billing procedures are followed.

Comment: Several commenters expressed concerns that implementing these regulations would result in an unrecoverable financial loss to nonprofit OPOs or an increase in the discard rate.

Response: The Medicare program has always tried to ensure that it pays only for the services furnished to its beneficiaries. Services furnished to other than Medicare beneficiaries should be paid by those patients or their third-party payers. We are not prohibiting an OPO from sending organs to a foreign country; we are simply not reimbursing these costs under the Medicare program. Section 1861(v)(1)(A) of the Act requires the Medicare program to pay only for the services furnished to Medicare beneficiaries.

While it is true that OPOs are at risk for any financial loss that may occur, we believe that there has been ample time for OPOs to set up memoranda of understanding or lines of credit with selected foreign transplant programs to ensure payment for these organs.

Comment: We received a comment that criticized excluding from Medicare payment the cost of kidneys "when all attempts to utilize the organs in Medicare beneficiaries have failed". The commenter believes that kidneys will be wasted.

Response: We agree that some of these kidneys may be wasted if not used in this country or sent to a foreign transplant center. Costs for kidneys that are wasted and not used either in this country or in a foreign country will be included in the OPOs' cost reports and paid by Medicare based on the ratio of Medicare kidneys to total kidneys. However, we believe that when a kidney is shipped to a foreign country and used in that country, the Medicare program should not be responsible for the cost of that kidney. Accordingly, if a kidney is sent to a foreign country, Medicare will not longer subsidize the cost of procuring that kidney.

Comment: In an effort to encourage the use of kidneys in this country rather than sending them to foreign countries, a commenter suggested that we increase the length of stay limits under the diagnosis related group (DRG). The commenter believes that this suggestion may encourage physicians to use kidneys that have been preserved longer than 40 hours.

Response: First, we believe it is necessary to point out Medicare does not have any length of stay limits for transplanation or for any other DRG. Secondly, Medicare has two methods that will allow a facility to receive additional reimbursement for atypical cases. Additional DRG payments are available to hospitals when the length of stay for a transplant exceeds a specific number of days, or when the cost of services exceeds prescribed thresholds (See §§ 412.82 and 412.84.). Accordingly, there is no payment barrier to the use of kidneys that have been preserved in excess of 40 hours and we see no reason to increase the DRG payment for these kidneys.

Comment: One commenter explained a long-standing reciprocal organ acquisition arrangement its OPO has with a U.S. military hospital in its area. The military renal transplant program (MRTP) is a recipient of kidneys for transplant from the OPO. The OPO and MRTP developed a Memorandum of Understanding due to the fact that military hospitals have no system that allows them to charge civilian OPOs for organ recovery costs. MRTP gets first choice on kidneys recovered from military hospitals, although only 44 of the 124 organs procured in the past 5 years were retained by the MRTP. Eighty organs were used by Medicare certified transplant centers. For kidneys retained by the MRTP, there are no charges by either the OPO or the military hospital for their respective organ recovery costs. Under this long-standing arrangement, the commenter believes its OPO would be adversely affected by the proposed regulation and increased costs to the OPO and the Medicare program would result.

Response: As a result of this long-standing arrangement that is beneficial to the Medicare program, we find it necessary to revise the proposed regulation so that equitable reimbursement to the OPO is maintained. Any special arrangement such as the one mentioned above that was in effect before March 3, 1988 (the publication date of the proposed rule) will be accepted. For these cases, the kidneys procured by an OPO at a military renal transplant hospital and retained for transplant at the hospital will be deemed as Medicare kidneys for cost reporting statistical purposes. While we know of no other special arrangements, if any similar arrangements existed before March 3, 1988, the OPO must submit a request to the fiscal intermediary for review and approval of these arrangements. Absent a special arrangement that existed before March 3, 1988, all kidneys sent to a non-Medicare institution are to be treated as non-Medicare kidneys.

Comment: A commenter stated that included in its hospital-based transplant program costs are a significant amount of pre-transplant costs and living related donor costs that would be partially excluded if a kidney was shipped to a foreign country or transplanted into a patient other than a Medicare beneficiary. The commenter suggested that these costs be removed before any computation that would eliminate the cost of kidneys sent to foreign countries or transplanted into patients other than Medicare beneficiaries.

Response: With respect to pre-transplant costs, we believe that the costs of laboratory tests for waiting list candidates are legitimate costs that should be included with the non-Medicare kidney cost allocation. Living related costs are normal hospital procurement costs that should be included in the overall cost. The amount of non-Medicare costs that will be removed will be a proportionate share of an average of the total costs incurred by the transplant center. In fact, living related acquisition costs are not significantly different from cadaveric acquisition costs. Based on these

considerations, we do not see the need for the more sophisticated recordkeeping system that this change will require.

Comment: One commenter questioned the proper handling of patients who are in their first 12 months of ESRD coverage and who are partially or totally covered by group health insurance. The commenter questioned if these secondary payer situations would be considered Medicare transplants or non-Medicare.

Response: We plan to treat secondary payer issues in exactly the same manner as we do all other hospital services. Specifically, if a beneficiary has primary insurance coverage and payment by the primary payer satisfies the liability of the Medicare program, the transplant will be considered a non-Medicare transplant for cost reporting purposes. If the primary payer does not satisfy all of the Medicare program's liability, the transplant will be considered a Medicare transplant for cost reporting purposes. This is consistent with Medicare billing and cost reporting instructions.

Comment: One commenter stated that it is possible for an OPO to sell an organ to a foreign transplant center in excess of its cost. The commenter believes that this situation conflicts with section 301 of the National Organ Transplant Act (Pub. L. 98–507), which prohibits the sale of human organs in excess of the cost to acquire them.

Response: We are also concerned with the sale of human organs for a profit. Even though this regulation is silent on the issue, we expect all intermediaries that discover what appears to be a profit-making arrangement, for not only kidneys but any human organs, to notify the Office of the Inspector General.

Comment: Several commenters mentioned that it is impossible for an OPO to know whether or not the recipient at the transplant center is a Medicare beneficiary.

Response: As stated in the proposed rule (53 FR 6674) any kidney sent to a Medicare-certified transplant center from an OPO will be assumed to be used for Medicare beneficiaries. Once the kidney is received by the transplant center, actual transplant experience will dictate the cost report treatment of these organs. In addition, as mentioned above, kidneys sent to U.S. military transplant hospitals will be treated as Medicare kidneys on the OPO's Medicare cost report.

IV. Provisions of this Final Rule

The regulation provisions of this final rule, for the most part, restate the regulation provisions of the proposed rule. The final rule differs from the proposed rule in that we—

- Replaced the term "organ procurement agency (OPA)" with "organ procurement organization (OPO)" to conform the language to final regulations that were published on March 1, 1988 (53 FR 6526) for OPOs and organ procurement protocols;
- Replaced the use of the term "harvest" with "procure" in response to comments we received; and
- Revised the examples we used in discussing the regulation provisions in response to concerns raised by commenters about military hospitals and the number of nonviable kidneys.

For the reasons explained in the proposed rule, we are adding a new regulation section (42 CFR 413.179) that applies to all OPOs and any Medicare-certified transplant centers that claim kidney acquisition costs on worksheet D–6 of the Hospital Cost Report (HCFA–2552). (42 CFR Part 413 was established on September 30, 1986, at 51 FR 34790.) We will require that kidneys sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries be excluded from Medicare payments to OPOs. OPOs that send kidneys to foreign countries must ensure that they receive the full amount from the foreign transplant centers for procurement and transportation of the kidneys. We will require OPOs to separate costs associated with kidneys that are sent to foreign countries or transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare fiscal intermediary. The fiscal intermediary will compute the ratio of the number of kidneys used for Medicare beneficiaries to the total number of kidneys used and adjust the costs for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries. For this purpose, kidneys furnished to other OPOs or Medicare-certified transplant centers in the United States will be assumed to be used for transplants in Medicare beneficiaries. As explained earlier in our response to a comment, we will treat kidneys sent to U.S. military institutions in the same manner as kidneys sent to any other Medicare-certified transplant centers from an OPO. Accordingly, any kidney sent to a Medicare-certified transplant center or to one of the two U.S military transplant centers by a certified OPO will be deemed to be a Medicare kidney for reimbursement purposes on the OPO's cost report. However, any costs associated with kidney transplants for patients other than Medicare beneficiaries that are performed in transplant centers will be excluded from total costs of the transplant centers, thereby excluding them from Medicare reimbursement. (The Medicare program will continue to pay for its proportionate share of costs incurred in procuring kidneys that were not transplanted.)

We issued contractor operating instructions to the Provider Reimbursement Manual (HCFA Pub. 15–2, Part II, Chapter 21) in January 1987 that require all OPOs to maintain a log detailing placement efforts effective February 4, 1987. (In the proposed rule, we inadvertently referred to January 1988 instructions.) This is intended to document the efforts that OPOs are making to place kidneys in Medicare beneficiaries before shipping kidneys overseas.

We have detailed below two examples using identical data that show the method of reimbursing OPOs for kidney acquisition costs under the current and revised methodologies.

Total Kidneys—130
Total Usable Kidneys—120
Total Nonviable Kidneys—10
Total Foreign Kidneys—20
Total Military Kidneys—10
Total VA Kidneys—10
Total Cost—$1,200,000 [1]
Foreign Revenue—$25,000 [2]
Military Revenue—$100,000
VA Revenue—$100,000
Payments from Other OPOS or Transplant Centers—$850,000

A. Current Methodology

Under the current methodology, the total cost of procuring kidneys is reduced by the revenue received and the balance is the amount due to or from the Medicare fiscal intermediary. Using the above data in the computation below, the amount the Medicare fiscal intermediary will pay the OPO will be $125,000 on final settlement.

[1] Included in the $1,200,000 total cost are costs associated with nonviable (unusable) kidneys. The Medicare program will continue to pay for its proportionate share of costs incurred in procuring kidneys that were not transplanted.

[2] It is expected that the revenue from the sale of kidneys to foreign countries will increase. As a result, the OPO will receive the same reimbursement in total, but more will come from the foreign country rather than from the Medicare program.

Total cost	$1,200,000
Less military, VA, and foreign revenue	−225,000
Subtotal	975,000
Less payments from Medicare OPOs and transplant centers	−850,000
Balance due OPO from intermediary	$125,000

B. Revised Methodology

Under the revised methodology, an OPO's total cost for all kidneys is reduced by the costs associated with kidneys transplanted in patients other than Medicare beneficiaries or sent to foreign countries regardless of income received from these sources. Using the above data in the computation below, the amount the OPO will pay the Medicare program at the end of the OPO's fiscal year is $50,000.

Step 1—Compute the Medicare Ratio

(Medicare Usable Kidneys) = (Total Usable Kidneys) − (Total Foreign & VA Kidneys)

90 = 120 − 30

$$\text{Medicare Ratio} = \frac{\text{Medicare Usable Kidneys}}{\text{Total Usable Kidneys}}$$

$$75 = \frac{90}{120}$$

Step 2—Compute Medicare Allowable Costs

Total cost (net of transportation costs for exported kidneys)	$1,200,000
Multiplied by Medicare ratio (.75)	X .75
Medicare costs	900,000
Less payments from OPOs, military hospitals, and transplant centers for Medicare kidneys	−950,000
Balance due Medicare Program from OPO	$(50,000)

In the above example, Medicare payments will decrease from $975,000 under the current system to $900,000 under the revised system. OPOs may recoup costs of kidneys from patients other than Medcicare beneficiaries or foreign countries that receive the kidneys.

IV. Regulatory Impact Statement

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any final regulations that are likely to meet criteria for a "major rule." A major rule is one that results in:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or any geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612), we prepare and publish a regulatory flexibility analysis for final regulations unless the Secretary certifies that the regulations will not have a significant impact on a substantial number of small entities. For purposes of the RFA, we consider OPOs to be small entities.

Currently, there are 72 OPOs, 50 of which are independent (that is, not hospital-based). We expect that the revised system will result in reduced payments to some OPOs, since the Medicare program will no longer subsidize the costs of kidneys that are sent to foreign countries or transplanted in patients other than Medicare beneficiaries. It will result in some program savings, estimated to be approxiamtely $1 million for the first full year of implementation of this regulation. While we expect that some OPOs will experience reductions in Medicare revenues, these reductions will not be substantial unless an OPO provides a disproportionately large number of kidneys to foreign countries. This rule will have an adverse effect on total revenue only if an OPO is unable to obtain payment for the costs associated with kidneys transplanted into patients other than Medicare beneficiaries or sent to foreign countries. We do not believe this is likely; rather, we believe that OPOs will be able to recover their costs not reimbursed by Medicare from patients other than Medicare beneficiaries and foreign transplant centers.

As discussed above, one potential consequence of this change will be an increase in the number of kidneys available for Medicare beneficiaries who need transplants. To the extent that this potential is realized, there will be resulting reductions in Medicare expenditures since patients can be transferred from more costly dialysis to less costly transplantation. These savings will be contingent on matching kidneys with appropriate recipients within a time period considered acceptable. To some extent this may depend on whether U.S. surgeons accept kidneys with a longer cold ischemic time for transplantation. Thus, the savings are not estimable.

We have determined that this regulation does not meet the criteria of E.O. 12291 and does not require a regulatory impact analysis. Also, we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a

substantial number of small entities. Therefore, a regulatory flexibility analysis has not been prepared.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 50 beds located outside a metropolitan statistical area. We have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on the operations of a substantial number of small rural hospitals.

V. Information Collection Requirements

This rule contains no information collection requirements, therefore, it does not come under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501).

VI. List of Subjects in 42 CFR Part 413

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Nursing homes, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set out in the preamble, Title 42, Part 413 is amended as follows:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services

1. The authority citation for Part 413 continues to read as follows:

Authority: Sections 1102, 1122, 1814(b), 1815, 1833(a), 1861(v), 1871, 1881, and 1886 of the Social Security Act as amended (42 U.S.C. 1302, 1320a–1, 1395f(b), 1395g, 1395l(a), 1395x(v), 1395hh, 1395rr, and 1395ww).

2. Section 413.179 is added to Subpart H to read as follows:

§ 413.179 Organ procurement organizations' (OPOs') or transplant centers' costs for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries

An OPO's or transplant center's total costs for all kidneys is reduced by the costs associated with procuring kidneys sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. OPOs, as defined in § 485.302 of this chapter, must separate costs for procuring kidneys that are sent to foreign transplant centers and kidneys transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare fiscal intermediaries. Medicare costs are based on the ratio of the number of usable kidneys transplanted into Medicare beneficiaries to the total number of usable kidneys applied to reasonable costs. Certain long-standing arrangements that existed before March 3, 1988 (for example, an OPO that procures kidneys at a military renal transplant hospital for transplant at that hospital), will be deemed to be Medicare kidneys for cost reporting statistical purposes. The OPO must submit a request to the fiscal intermediary for review and approval of these arrangements.

(Catalog of Federal Domestic Assistance Program No. 13.773, Medicare Hospital Insurance and No. 13.774, Supplementary Medical Insurance)

Dated: September 18, 1988.

William L. Roper,

Administrator, Health Care Financing Administration.

Approved: November 21, 1988.

Otis R. Bowen,

Secretary.

[FR Doc. 89–2700 Filed 2–3–89; 8:45 am]

BILLING CODE 4120–03–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 88–153; RM–6273]

Radio Broadcasting Services; McFarland, CA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document substitutes Channel 275B1 for Channel 275A at McFarland, California, and modifies the Class A license of Caballero Spanish Media, Inc. for Station KXEM–FM, as requested, to specify operation on the higher class channel, thereby providing that community with its first wide coverage area FM service. Reference coordinates for Channel 275B1 at McFarland are 35–29–33 and 119–11–43. With this action, the proceeding is terminated.

EFFECTIVE DATE: March 16, 1989.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 88–153, adopted December 14, 1988, and released January 30, 1989. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857–3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments for California, is amended by revising the entry for McFarland by deleting Channel 275A and adding Channel 275B1.

Federal Communications Commission.

Steve Kaminer,

Deputy Chief, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 89–2724 Filed 2–3–89; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 73

[MM Docket No. 88–32; RM–6029]

Radio Broadcasting Services; Linton, IN

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document substitutes Channel 227B1 for Channel 228A at Linton, Indiana, and modifies the Class A license of Linton Broadcasting Company, Inc. for Station WQTY(FM), as requested, to specify operation on the higher class channel, thereby providing that community with its first wide coverage area FM service. Reference coordinates for Channel 227B1 at Linton are 38–56–46 and 87–18–40. With this action, the proceeding is terminated.

EFFECTIVE DATE: March 16, 1989.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 634–6530.